FDA 510(k) Premarket Notification

K233010 Beagank 4T Plus

CLEARED

Nov 21, 2023
60 days to decision

K233010 · Product code: **NFO** · Neurology
Source: https://www.510kdatabase.net/k233010/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Transcutaneous Electrical, Aesthetic Purposes (NFO)
Date received	Sep 22, 2023
Decision date	Nov 21, 2023
Days to decision	60 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Belega, Inc.**
Location	Kita-Ku, JP
Contact	Masayuki Okumura
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	**Ken Block Consulting Co., Ltd.**
Contact	Nana Nagashita

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov